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Original Article

The effect of osteoporosis education on osteoporosis knowledge level and daily life in Parkinson's disease patients: A 12-week, randomized-controlled trial

Muhammed Abdulkerim Şahin[1], Mustafa Doğukan Aydemir[2], Berril Dönmez Çolakoğlu[3], Raif Çakmur[3], Belgin Ünal[4], Selmin Gülbahar[2]

[1]Department of Physical Medicine and Rehabilitation, Division of Rheumatology, Istanbul University-Cerrahpaşa, Cerrahpaşa Faculty of Medicine, Istanbul, Türkiye
[2]Department of Physical Medicine and Rehabilitation, Dokuz Eylül University Faculty of Medicine, Izmir, Türkiye
[3]Department of Neurology, Dokuz Eylül University Faculty of Medicine, Izmir, Türkiye
[4]Public Health, Dokuz Eylül University Faculty of Medicinee, Izmir, Türkiye

ABSTRACT

Objectives: This study aims to evaluate the effect of osteoporosis education on osteoporosis knowledge level (OKL) and behavioral changes in daily life in patients with Parkinson's disease (PD).

Patients and methods: Between May 2019 and December 2019, a total of 54 patients (34 males, 20 females; median age: 68.5 years; range, 50 to 87 years) were included in the study. We randomly assigned in a 1:1 ratio, patients with PD to receive either only the brochure or in addition to this a verbal osteoporosis education. The patients were randomized into the control (n=27) and intervention groups (n=27). Seven of the patients (two in the control group and five in the intervention group) were lost to follow-up. The patients were assessed at baseline and Week 12. The primary outcomes were Physical Activity Scale for the Elderly (PASE) score (0-400) and daily calcium intake (DCI). The secondary outcomes were revised 2011 osteoporosis knowledge test (rOKT) score (0-32), frequency of falls, smoking and alcohol use at Week 12.

Results: The median total PASE score was 81 (range, 0 to 205) for the intervention group, compared to 61 (range, 0 to 242) for control group at Week 12. There was no statistically significant difference between the groups at Week 12, except for the medians of the frequency of falls that was significantly lower in the intervention group ($p<0.05$). A significant improvement from baseline was observed in the median rOKT scores (control group 16 (range, 6 to 21) to 19 (range, 11 to 25); intervention group 13 (range, 6 to 24) to 18 (range, 9 to 24); $p<0.001$) and DCI (control group 855 (range, 420 to 1,640) to 890 (range, 550 to 1,660); intervention group, 870 (range, 400 to 1,385) to 1,020 (range, 400 to 1,940) mg/day; $p<0.01$) in both groups. Also, a significant improvement in the leisure activities (PASE subgroup) was observed in the intervention group ($p<0.05$).

Conclusion: Osteoporosis education had some positive effects in patients with PD, even when only given the brochure. With additional verbal education, more benefits can be obtained.

Keywords: Daily calcium intake, frequency of falls, knowledge level, osteoporosis education, Parkinsonian, physical activity.

Osteoporosis is a metabolic bone disease characterized by decreased bone mass and impaired bone microarchitecture, resulting in bone fragility and increased risk of fracture. There are some risk factors and secondary causes of osteoporosis, including advanced age, female sex, white skin, postmenopausal status, maternal history, sedentary life, smoking-alcohol use, insufficient calcium and vitamin D intake, medications used and Parkinson's disease (PD). The main treatment tools are medical treatment, adequate calcium and vitamin D intake, exercise, preventive measures, smoking and alcohol cessation.[1]

Parkinson's disease is a common, neurodegenerative disease seen in the elderly population with an estimated prevalence of approximately 1% over 60 years of

Corresponding author: Muhammed Abdulkerim Şahin, MD. İstanbul Üniversitesi-Cerrahpaşa, Cerrahpaşa Tıp Fakültesi Fiziksel Tıp ve Rehabilitasyon Anabilim Dalı Romatoloji Bilim Dalı, 34098 Fatih, İstanbul, Türkiye.
E-mail: md.abdulkerim@gmail.com

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age.[2] Its main features are resting tremor, rigidity, bradykinesia, and postural instability. Decreased mobility and malnutrition can also be seen in the later stages. These symptoms are thought to be the main risk factor for conditions such as decreased bone mass, increased frequency of falls and fractures in patients with PD. It has been shown that osteoporosis is frequently seen in patients with PD and it is one of the chronic diseases with the highest risk of fracture, mostly in the hip.[3]

Although patient education, as a prevention and treatment method, is not a sufficient method alone to create behavior change, some behavioral changes may occur if the individual's decision to control the disease develops. This is called self-management. Self-management has been used successfully in chronic diseases. In this respect, it is of great importance for osteoporosis to inform patients about daily life habits that affect bone health, such as nutrition, physical activity, anti-fall measures, alcohol and smoking cessation.

There are several studies in the literature on the effects of various educational programs for osteoporosis.[4-23] However, no study has been found investigating the effects of a training program for osteoporosis, specifically for PD. Effective educational methods for osteoporosis are also needed in patients with PD, as it is associated with an increased risk of osteoporosis and fractures. In addition, considering that cognitive and locomotor problems in patients with PD may have significant effects on educational outcomes, in the present study, we aimed to evaluate the effect of osteoporosis education on osteoporosis knowledge level (OKL) and behavioral changes in daily life in patients with PD. We hypothesized that there was a statistically significant difference between giving informative brochures about the osteoporosis alone and additionally providing verbal osteoporosis education to patients with PD in terms of the effects on OKL and daily life.

PATIENTS AND METHODS

Study design

This single-center, single-blind, 12-Week, randomized-controlled study (RCT) was conducted at Dokuz Eylül University Faculty of Medicine, Department of Physical Medicine & Rehabilitation (PMR) and Neurology Clinics between May 2019 and December 2019. Eligible patients aged 50 years or older who had a diagnosis of PD were included. Those having severe cognitive and/or physical disability were excluded. Finally, a total of 54 patients (34 males, 20 females; median age: 68.5 years; range, 50 to 87 years) were included in the study. The patients were randomized into the control (n=27) and intervention groups (n=27). Seven of the patients (two in the control group and five in the intervention group) were lost to follow-up (Figure 1).

A structured questionnaire was administered to the participants by face-to-face interview at baseline. Then, patients were randomly assigned in a 1:1 ratio to receive only the educational brochure (DEU Osteoporosis School [DOPS]) or in addition to this a single session of verbal osteoporosis education (DEU Osteoporosis Education Program [DOPEP]). At Week 12, the groups were evaluated with the same questionnaire as at baseline. The investigator who made the assessments was blinded to the intervention. A block randomization list created using a computer program was used to place the participants in the control and intervention groups.[24]

Intervention

Our brochure (DOPS) was containing general information about and prevention methods of osteoporosis. The same information as DOPS was included in the verbal education (DOPEP). DOPS and DOPEP were prepared by DEU PMR Department. The verbal education (DOPEP) lasts about 30 min and was applied by the PMR physician researcher in the PMR outpatient clinic. The education was held in the form of a single session with a slide show and verbal narration by face to face with groups of 5 to 10 patients, having a question and answer part, as well. While the program was being prepared, the National Osteoporosis Foundation (NOF) data, FRACTURK study,[25] Republic of Türkiye, Ministry of Health publications (Physical Activity Guide, Turkey Nutrition Guide TUBER 2015, Adults Physical Activity Guide in Chronic Diseases, Calcium, Vitamin D and Osteoporosis) was used.

Topics covered by DOPS and DOPEP

Definition of osteoporosis, course of bone mass with age, bone density measurement, osteoporosis complications, statistical data on osteoporosis, osteoporosis risk factors, self-management methods, balanced diet, adequate calcium and vitamin D intake, general physical activity recommendations, weight-bearing exercises (five days a week, 30 min, moderate intensity activities; brisk walking, jogging, climbing stairs, climbing uphill, heavy housework, light gardening), fall prevention measures, quitting smoking, and alcohol use.

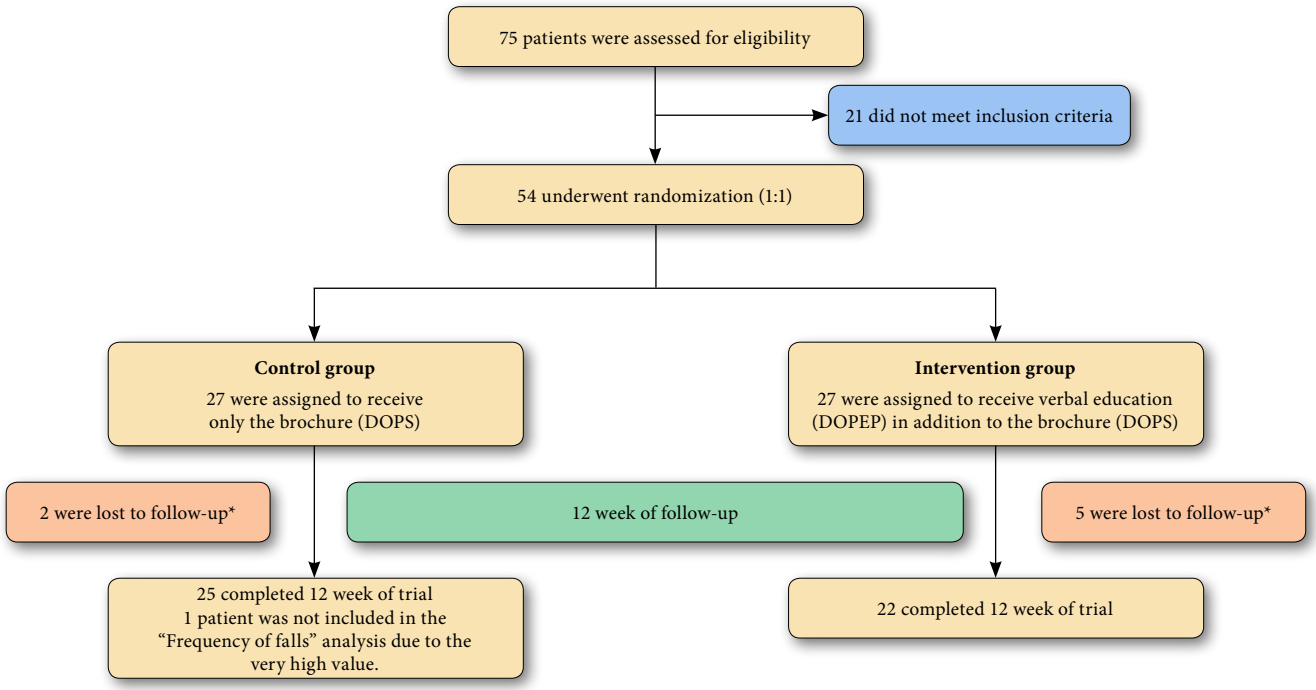

Figure 1. Randomization, treatment, and follow-up.

DOPS: Dokuz Eylül University Osteoporosis School; DOPEP: Dokuz Eylül University Osteoporosis Education Program; * All of the patients who were out of follow-up were included in the evaluation with intention to treat analysis.

Outcome measures

The data were obtained from the self-reports of the patients by face-to-face interview method.

At baseline and at Week 12; Physical Activity Scale for the Elderly (PASE) score, daily calcium intake (DCI), revised 2011 osteoporosis knowledge test (rOKT) score, frequency of falls, smoking and alcohol use status and amounts were recorded. While measuring OKL with rOKT, the effect on daily life was evaluated by PASE, DCI, frequency of falls, and smoking and alcohol use status and amount results.

One of the primary outcomes was PASE score at Week 12. It is a widely used scale with proven validity and reliability to evaluate the level of physical activity in individuals aged 65 and over.[26] It has three subgroups as leisure time activities (LTAs; sitting activities, walking, light sport/activity/worship, moderate sport/entertainment, heavy sport/entertainment, muscular strength and endurance exercises), household activities (HAs; light household chores such as ironing, meal preparation, dishwashing; heavy household chores such as vacuuming, wiping floors, washing cars; and home repairs, gardening, child or disabled care etc.) and work-related activities (WRAs). It consists of questions covering a wide variety of activities, from light to heavy. It questions the intensity, frequency and duration of the activities performed in the last seven days. In the calculation, there is a certain activity load coefficient according to the difficulty level of each activity.[27] These coefficients are multiplied by the average daily duration of the activities and all results are added. The total score is between 0 and 400 or more. A higher score indicates higher physical activity. The Turkish validity and reliability have also been conducted.[28]

The other primary outcome was DCI at Week 12. In DCI calculation scale of NOF, dairy products (milk, yogurt, cheese), calcium-rich vegetables and supplemental calcium products are questioned. A total of 250 mg is added as a standard to the amount obtained (for other calcium containing foods consumed during the day). Each serving of dairy group products contains 300 mg of calcium, and portions are as much as 8 oz milk, 6 oz yogurt, and 1.5 oz cheese. These values are recalculated as 1 cup/240 mL for milk, 1 small bowl/177 mL for yogurt, and 2 matchboxes/45g for cheese by using unit conversions (ounces → grams and milliliters). While

calculating calcium-rich vegetables, the calculation was made on the amount of calcium in 1 bowl of cooked 10 of them (black cabbage 256 mg, broccoli 200 mg), and kale 175 mg etc.). The total score obtained is determined as DCI.

Secondary outcomes were defined as rOKT score, frequency of falls, and smoking and alcohol use status and amount at Week 12. The rOKT is an updated version of OKT which was developed in 1991. It has validity and reliability.[29] The Turkish validity and reliability have also been conducted.[30] It is a 32-item questionnaire measuring OKL. The first 11 questions question osteoporosis risk factors. The answers are given by ticking the options "It is highly likely to have osteoporosis", "It has nothing to do with the development of osteoporosis", "The probability of osteoporosis is low" and "I don't know". Each correct answer is awarded 1 point. Other questions have four options and 1 point is given for the correct answer. The total score is between 0 and 32.

To determine frequency of falls, the participants were asked how many times they fell within the last four weeks.

Smoking and alcohol use status was evaluated with Yes/No options. Amount of smoking and alcohol use was evaluated with the average daily (package cigarette and unit alcohol) consumption amounts within the last one week.

Statistical analysis

Study power analysis and sample size calculation were performed using the G*Power version 3 (Heinrich-Heine-University Düsseldorf, Düsseldorf, Germany).[31] We calculated that a sample of 52 patients (26 in each group) would provide the trial with 80% power, at a two-sided significance level (p) of 0.05 and the conventional effect size was considered to be large (d=0.8), to detect a large intervention difference of the PASE scores at Week 12, as there were no similar studies in the literature.

Statistical analysis was performed using the SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in median (min-max) or number and frequency, where applicable. The chi-square test was used to evaluate demographic characteristics of both groups, Hoehn & Yahr Stage, and osteoporosis awareness at baseline. At baseline and Week 12, smoking and alcohol use status were compared between the groups using Chi Square test. The Mann-Whitney

TABLE 1
Baseline demographic and clinical characteristics of the patients

	Control group (n=27)				Intervention group (n=27)				
Characteristic	n	%	Median	Min-Max	n	%	Median	Min-Max	*p*
Age (year)			70	50-87			65	50-83	0.15
Sex									
Male	17	63			17	63			1.0
Marital status									0.48
Married	23	85			21	78			
Widow	4	15			6	22			
Education level									0.15
Illiterate	0	0			4	14.8			
Primary school	11	40.7			5	18.5			
Middle school	2	7.4			3	11.1			
High school	6	22.2			5	18.5			
University	8	29.6			10	37			
Hoehn & Yahr Stage*									0.58
1	13	48.1			13	48.1			
1.5	4	14.8			6	22.2			
2	10	37			7	25.9			
3	0	0			1	3.7			
Osteoporosis awareness**	14	52			16	59			0.58

* The Hoehn & Yahr Scale is used to measure how Parkinson's disease symptoms progress and the level of disability. There are 5 stages 1 to 5 and the stage increases as the disease progresses;[31] ** Osteoporosis awareness questioned with question that "Have you heard of osteoporosis disease before?" (Yes/No); *P* values determined using Mann-Whitney U test for continuous data and Pearson chi-square test for categorical data.

U test was used to compare age of both groups at baseline and DCI, frequency of falls, PASE score, rOKT score, and amount of smoking and alcohol use between the groups at baseline and Week 12. The Wilcoxon test was used to analyze intra-group differences. The McNemar test was used to compare intra-group categorical data at baseline and Week 12. As the median rOKT scores was significantly higher in the control group at baseline, the amount of intra-group changes was further compared using

TABLE 2
Primary and secondary outcomes; within group and between groups differences

	Control group (n=27)					Intervention group (n=27)					
	n	%	Median	Min-Max	p^a	n	%	Median	Min-Max	p^a	p^b
Primary outcome											
PASE (Total)											
Baseline			64	0-207	0.22			81	0-202	0.28	0.89
12 w			61	0-242				81	0-205		0.89
PASE-LTA											
Baseline			8.6	0-57	0.22			2.2	0-60	0.048*	0.13
12 w			8.6	0-57				8.6	0-57		0.37
PASE-HA											
Baseline			50	0-136	0.49			50	0-171	0.89	0.60
12 w			50	0-136				50	0-171		0.67
PASE-WRA											
Baseline			0	0-120	0.65			0	0-150	1.0	0.18
12 w			0	0-180				0	0-150		0.31
DCI (mg)											
Baseline			855	420-1640	0.006*			870	400-1385	0.001*	0.95
12 w			890	550-1660				1020	400-1940		0.42
Secondary outcomes											
rOKT											
Baseline			16	6-21	<0.001*			13	6-24	<0.001*	0.01*[c]
12 w			19	11-25				18	9-24		0.23
Frequency of falls[d]											
Baseline			0	0-3	0.74			0	0-1	0.15	0.06
12 w			0	0-3				0	0-1		0.02*
Amount of smoking, package/day											
Baseline			0	0-1	0.31			0	0-1.5	0.046*	0.15
12 w			0	0-1				0	0-1.5		0.31
Amount of alcohol use, unit/day											
Baseline			0	0-1	0.31			0	0-4	0.027*	0.15
12 w			0	0-1				0	0-2		0.40
Smoking status											
Baseline	3	11			1.0	6	22			0.25	0.27
12 w	2	7				3	11				0.64
Alcohol use status											
Baseline	3	11			1.0	7	26			0.25	0.16
12 w	2	7				4	15				0.38

w: Week; PASE: Physical Activity Scale for the Elderly; LTA: Leisure time activity subgroup; HA: Household activity subgroup; WRA: Work-related activity subgroup; DCI: Daily calcium intake according to the National Osteoporosis Foundation; rOKT: Revised 2011 Osteoporosis Knowledge Test score; [a] within-group difference between baseline and 12 weeks, were calculated using Wilcoxon test for continuous data and McNemar test for categorical data; [b] difference between groups, determined using Mann-Whitney U test for continuous data and Pearson chi-square test for categorical data; [c] The median of rOKT scores was significantly higher in the control group at baseline. For this reason, the amounts of within-group change were also compared between groups using the Mann-Whitney U test and no significant difference was found. (p=0.34); [d] Frequency of falls in the last 4 weeks analyzed on 26 participants for the control group by omitting the high value (150) in this group; * Statistically significant *p*-values, the level of significance was set at 0.05.

the Mann-Whitney U test. The very high value (150 times/4 weeks) in the frequency of falls of a participant in the control group was not included in the statistical analysis and the control group was evaluated over 26 individuals in terms of frequency of falls. A *p* value of <0.05 was considered statistically significant.

Of the 54 participants included in the study, 7 (2 of them control group, 5 of them intervention group) were lost to follow-up (Figure 1). Intention to treat analysis was performed assuming that there was no change in the data of these participants at Week 12 compared to baseline.

RESULTS

Baseline demographic and disease characteristics of the patients including Hoehn & Yahr Stages and osteoporosis awareness were similar in both groups (Table 1). There was no statistically significant difference between the groups at baseline in terms of PASE score, DCI, frequency of falls, smoking and alcohol use status and amount values. However, the median of rOKT scores was significantly higher in the control group at baseline (p<0.05). Therefore, the amount of intra-group changes was also compared between the groups for rOKT score, and no significant difference was found (Table 2).

Considering the primary outcomes, there was no statistically significant difference between the groups at Week 12 in the median total PASE scores and DCI scores. Also, total PASE scores remained unchanged significantly within the groups from baseline to Week 12 (Figure 2). A statistically significant improvement from baseline was observed in the median scores for DCI in both groups (p<0.05) (Figure 3). In the intervention group, a statistically significant increase in the median values of the LTAs (PASE subgroup) was observed (p<0.05) (Table 2, Figure 2).

Considering the secondary outcomes, there was no statistically significant difference between the groups at Week 12, except for the frequency of falls. The median value of frequency of falls was significantly lower in the intervention group at Week 12 (p<0.05). A statistically significant improvement from baseline was observed in the median scores for rOKT in both groups (Figure 4). In the intervention group, a statistically significant decrease in the median value of the amount of smoking and alcohol use was observed (p<0.05) (Table 2).

DISCUSSION

The effects of osteoporosis education have not been previously investigated in patients with PD. In our study, some positive effects of osteoporosis education on both OKL and daily life were observed.

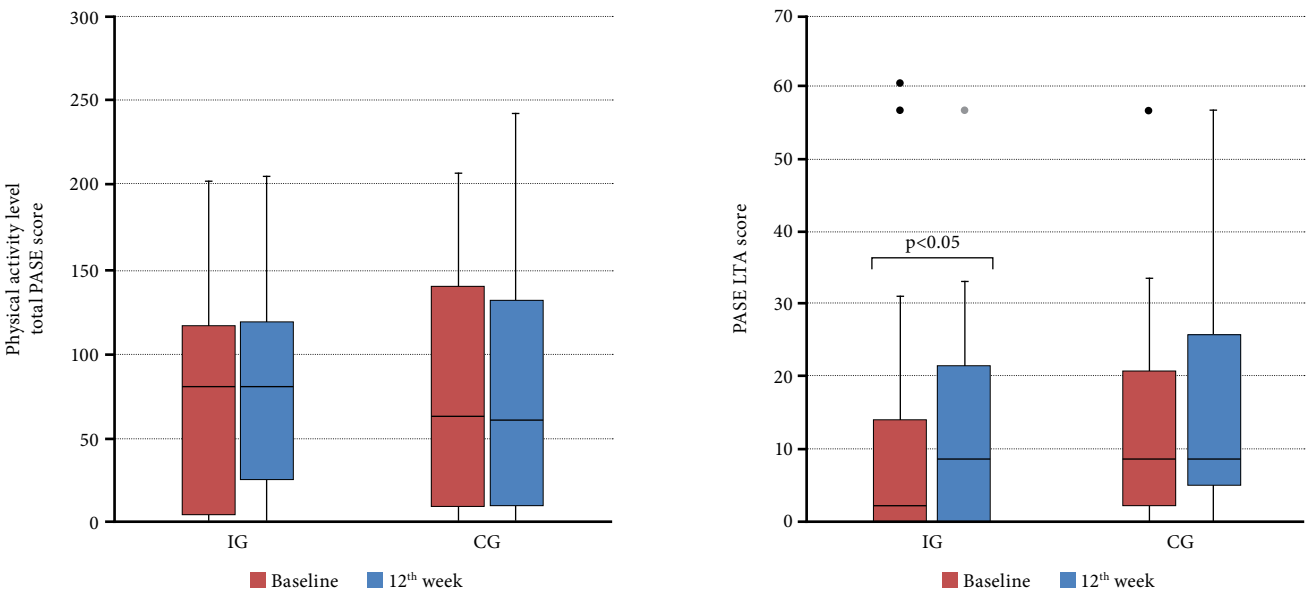

Figure 2. Box and whisker plot showing the median, IQR and min-max values of total PASE and PASE LTA subgroup scores. The horizontal line displays the median, the box-edges show the 25th and 75th percentiles and the whiskers show the smallest and highest value within 1.5 box lengths from the box. Points mark outliers. P<0.05 value was statistically significant.

IG: Intervention group; CG: Control group; IQR: Interquartile range; PASE: Physical Activity Scale for the Elderly; LTA: Leisure time activity.

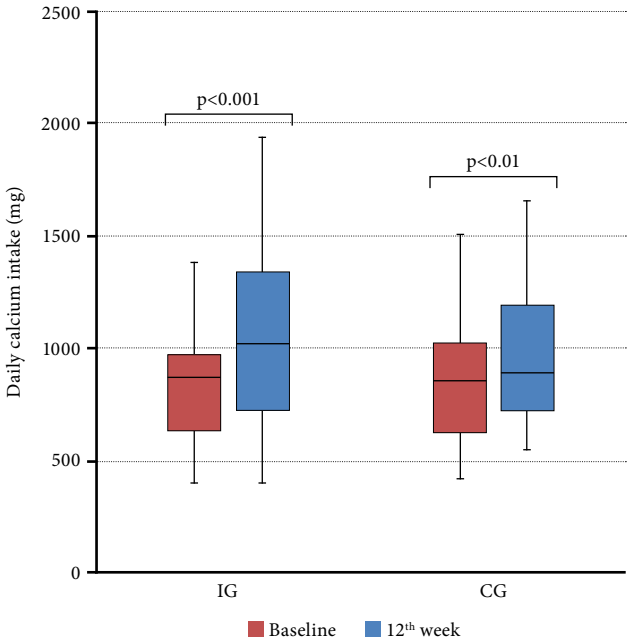

Figure 3. Box and whisker plot showing the median, IQR and min-max values of daily calcium intake. The horizontal line displays the median, the box-edges show the 25th and 75th percentiles and the whiskers show the smallest and highest value within 1.5 box lengths from the box. Points mark outliers. P<0.05 value was statistically significant.

IG: Intervention group; CG: Control group; IQR: Interquartile range.

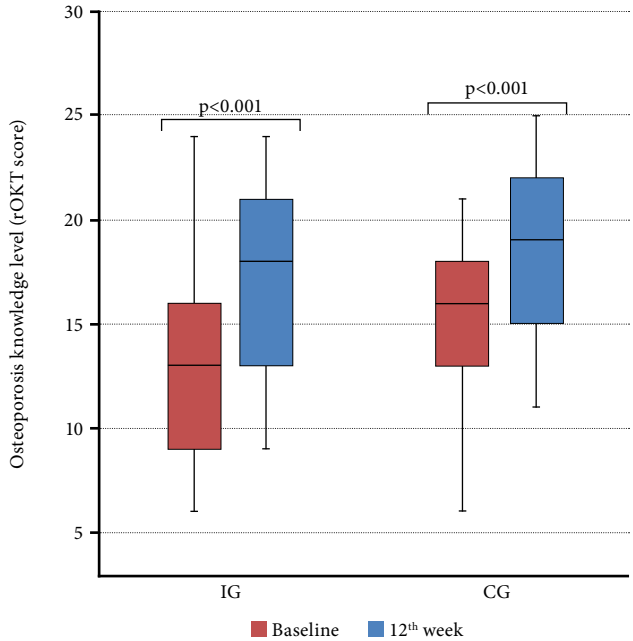

Figure 4. Box and whisker plot showing the median, IQR and min-max values of rOKT scores. The horizontal line displays the median, the box-edges show the 25th and 75th percentiles and the whiskers show the smallest and highest value within 1.5 box lengths from the box. P<0.05 value was statistically significant.

IG: Intervention group; CG: Control group; IQR: Interquartile range; rOKT; Revised 2011 Osteoporosis Knowledge test.

Based on these findings, we can speculate that osteoporosis education in patients with PD is an important method to develop self-management related to prevention and treatment of osteoporosis.

In the current study, the male-to-female ratio was 1.7. This ratio is approximately 1.5 for PD in the literature.[33] In our control and intervention group, the rate of osteoporosis awareness was 52% and 59%, respectively. In the literature, this rate varies widely (54 to 88%).[34-36]

There are several studies in the literature investigating the effect of different osteoporosis education methods on physical activity with different evaluation methods (exercise behaviors,[12] physical activity,[23] weekly exercise frequency,[15] doing more than 30 min of aerobic exercise 0-1, 2-4, 5-7 days a week,[18] reporting an increase in exercise),[19] and osteoporosis education does not have a significant effect on physical activity in these studies. In Schousboe et al.'s[20] study, while brochures were given to the control group alone, 15 min of one-to-one osteoporosis education was given to intervention group by the nurses in addition to the brochure, and it was concluded that the ratio of patients who reported an increase in the frequency of weight-bearing exercise was significantly higher in the intervention group.

In our study, there was no significant difference in the PASE total and HA and WRA subgroup scores between the groups at Week 12. We believe that this is due to reasons such as the PD and high average age of the patients those limits the physical activity level, also the early retirement age, the difficulty of changing profession or transitioning to a new job and the traditional housework and occupational activity distributions of men and women.

However, in the LTA subgroup, a significant increase was observed in the intervention group, which is different from the literature. We believe that this may be due to the difference in our measurement method. In many studies, the change in physical activity was measured by the general word "exercise" and the change was measured by asking the patient. Nevertheless, in our study, the patient was asked about the current

activity status, not the change, and also a detailed questioning was made. Both the frequency and duration of the activities were questioned. We believe that this helps us to obtain more realistic data for the determination of physical activity level. The difference in the results may also be related to the education methods and follow-up periods. In addition to these, we believe that it is possible to increase physical activity more through personalized, one-to-one rather than in groups, more intense, longer and applied training programs.

In our study, a significant increase occurred in both control group and intervention group in DCI. The median values were 855 mg in the control group and 870 mg in the intervention group at baseline. Although there are no data for Türkiye in the compilation of the 2017 International Osteoporosis Foundation Calcium Steering Committee, DCI values of Italy (765 mg), Spain (789 mg), Jordan (856 mg), and Iran (859 mg), which are geographically closest to Türkiye, are close to our study data.[37] In addition, study data of Foldi et al.[15] from United States (846 mg) is close to our study.

It is thought that the increase in DCI may reduce the need for calcium supplementation. Considering that the daily calcium requirement (DCR) is 1200 mg,[1] in our study, the number and ratio of individuals meeting DCR through nutrition increased from 3 (11%) to 9 (37%) in the intervention group and from 3 (11%) to 5 (19%) in the control group. In the Morfeld et al.'s[23] review of 15 RCT, including those with a diagnosis of osteoporosis or risk factors for osteoporosis, more than 50% of the studies showed significant results in favor of the intervention group in calcium intake. No interventions or routine applications such as brochures were made to the control group in the studies. In Foldi et al.'s[15] study, 10 min of video osteoporosis education increased DCI from 846 mg to 1,113 mg and the number and ratio of individuals meeting DCR increased from 7 (20%) to 13 (38%).

In our study, unlike other studies, a brochure was given to the control group and a significant increase was observed in DCI. There was no significant difference between the DCI values of both groups at Week 12. It is thought that giving only educational brochure in patients with PD may be a cost-effective method to increase DCI.

In the current study, the increase in OKL was statistically significant in both groups ($p<0.001$). In the Morfeld et al.'s[23] review, more than 50% of the studies showed significant results in favor of the intervention group in OKL. In the Francis et al.'s[9] RCT, osteoporosis education and course booklet were given to the intervention group and there was a significant increase in intervention group compared to the control group. In the Nielsen et al.'s[16] study, a 12-h education program was applied and the effects on OKL were examined. While an increase was observed in the intervention group, no significant change was observed in the control group.

In the Gaines et al.'s[12] and Yuksel et al.'s[22] studies, intervention groups were given education and brochures. The OKL was evaluated with the Facts on Osteoporosis Quiz and there was no significant difference between the groups. These results may be due to the scale used and the long follow-up periods (two years for Gaines et al.'s[12] study).

Our study differs from other studies in that we also gave brochures to control group, and the brochure was found to be effective on its own to increase OKL. There was no significant difference between the groups in the amount of OKL increase within the group, and we believe that only giving brochures (DOPS) to patients with PD may be a cost-effective method to increase OKL.

In the literature, there is a limited number of studies examining the effect of osteoporosis education on this issue. In the Foldi et al.'s[15] study, osteoporosis education did not cause a significant change in the number of smokers and the alcoholics who drank every week. In the Pekkarinen et al.'s[18] study, there was a significant difference between the smoker and non-smoker groups for 10 years.

In our study, no significant change was found in smoking and alcohol use status in both groups. The elimination of addictions is often possible with intense and long-term behavioral, psychosocial, and medical interventions.[38,39] Considering the amount of smoking and alcohol use, there was no significant change in the control group, but there was a significant decrease in the intervention group (cigarette $p=0.046$, alcohol $p=0.027$). However, we believe that our sample size was not sufficient to determine these outcomes.

As in our study, there is no study evaluating the effect of osteoporosis-specific education on the frequency of falls. Therefore, it is not possible to directly compare our results with the literature in this respect. According to a Cochrane systematic review examining the effectiveness of fall prevention interventions in the elderly, group and home-based

exercise programs and home safety modifications significantly reduced the frequency and risk of falls.[40] However, education programs or studies that increased the level of knowledge about fall precautions alone did not significantly reduce the frequency and risk of falls. Another review of 54 RCTs confirmed that at least 2 h of moderate to heavy balance exercise per week alone prevents falls.[41]

In our study, there was no statistically significant decrease in the frequency of falls in both groups. However, the frequency of falls was significantly lower in the intervention group compared to the control group at Week 12. We believe that a number of factors such as the fact that baseline frequency of falls was lower in the intervention group, insufficiency of the number of volunteers for this outcome, taking into account only the frequency of falls in the last four weeks and factors such as PD and advanced age may have had an effect on this result. The positive effect of verbal education can be attributed to the weight-bearing exercise recommendations described in conjunction with fall prevention measures. This result also suggests that reducing the frequency of falls can be achieved with longer-term and applied programs.

Nonetheless, there are some limitations to this study. First, no intervention control group was not formed for ethical reasons, and since the control group was given a brochure, the difference between the groups decreased. Second, the follow-up period was limited to three months, which did not allow measurement of long-term results. The reason for this limitation, which was deliberately made by us, was the presence of other possible conditions (cognitive, locomotor, cardiopulmonary, etc.) that are likely to be encountered due to disease progression and advanced age in patients with PD and that may affect the results. Third, incorporating objective evaluations such as Timed Up and Go, Chair Stand tests or balance assessments could further strengthen the evidence on the effects of osteoporosis education in PD patients. These objective measures could provide additional insights into the overall impact of the intervention on functional mobility and fall prevention. Finally, the insufficient number of volunteers for statistics on smoking and alcohol use and taking into account only the frequency of falls in the last four weeks. In osteoporosis or geriatric studies, the most optimal time frame to obtain self-reported falls appears to be a period of 12-month, and we usually recall the number of falls we have had in the last year. However, since we were dealing with PD patients, we asked the patients for the last four weeks.

The main strength of our study is that it is the first study to investigate the effects of osteoporosis education in patients with PD. Other strengths of our study are that it is a RCT, assessor-blinded study, with the adequate number of patients, and the use of PASE score which allowed detailed inquiries to determine physical activity.

In conclusion, the brochure alone given for osteoporosis education in patients with PD can provide a significant increase in OKL and DCI. In addition to the brochure, a verbal education program can be used to improve physical activity, amount of smoking and alcohol use and frequency of falls. Further large-scale studies with longer follow-up period, more intensive and applied education methods, more objective evaluation methods and a no intervention group are warranted to confirm these findings.

Ethics Committee Approval: The study protocol was approved by the Dokuz Eylül University Non-invasive Research Ethics Committee (date: 08.05.2019, no: 2019/12-03). Clinicaltrials.gov (NCT04536610), August 28, 2020. Retrospectively registered. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Concept, design, writing manuscript, critical review: M.A.Ş., S.G.; Supervision: S.G.; Literature search, analysis: M.A.Ş., S.G., B.Ü.; Materials, resources: M.A.Ş., S.G., R.Ç., B.D.Ç.; Data collection and/or processing: M.A.Ş., S.G., M.D.A., B.Ü.

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